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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,084	03/27/2001	Michael A. Evans	19744P001120	2528

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EXAMINER

ODLAND, KATHRYN P

ART UNIT PAPER NUMBER

3743

DATE MAILED: 01/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/820,084

Applicant(s)

EVANS ET AL.

Examiner

Kathryn Odland

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-94 is/are pending in the application.
- 4a) Of the above claim(s) 6,7,9,11-44,46,47 and 49-94 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8,10,45 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4-6. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I and Species 2 in Paper No. 8 is acknowledged. Claims 1-5, 8, 10, 45, and 48 are under consideration. Claims 6, 7, 9, 11-44, 46, 47 and 49-94 are withdrawn from consideration.

Response to Amendment

The amendments to the specification, title, and drawings are acknowledged.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-4, 8, 10, 45, and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Lary in US 2002/0082592.

Regarding claim 1, Lary discloses a device for percutaneously exposing an outer layer of a body lumen or body cavity of a patient which is covered by an inner layer having a catheter body (22) having a proximal end, a distal end and a lumen therethrough; and a dissection tool (36) disposed near the distal end of the catheter

body adapted to expose a portion of the outer layer, as recited on pages 3 and 4 and seen in figures 2-9G.

Regarding claim 2, Lary discloses that as applied to claim 1, as well as, a body lumen that is a blood vessel, the inner layer is an intimal layer and the outer layer is an adventitial layer, as recited in sections [0020]-[0022] and [0044]-[0053].

Regarding claim 3, Lary discloses that as applied to claim 2, as well as, a dissection tool (36) that is a radially expansive element configured to contact the vessel wall in an expanded position, as recited on pages 3-5.

Regarding claim 4, Lary discloses that as applied to claim 3, as well as, a radially expansive element (36) that is a cutting surface configured to cut through the intimal layer of the vessel wall to expose a portion of the adventitial layer after contact with the vessel wall in the expanded position, as recited on pages 3-5 and seen in figures 2-9G.

Regarding claim 8, Lary discloses that as applied to claim 3, as well as, a radially expansive element that is advaceable along the exposed portion of the adventitial layer to delaminate the intimal layer from the adventitial layer along a segment of the blood vessel, as recited on pages 3-5 and seen in figures 2-9G.

Regarding claim 10, Lary discloses that as applied to claim 3, as well as, a radially expansive element that is expandable by action of an inflatable member (such as balloons), as recited on pages 3-5 and seen in figures 2-9G.

Regarding claim 45, Lary discloses that as applied to claim 2, as well as, a dissection tool that is configured to advance along the exposed portion to delaminate the intimal layer from the adventitial layer along a segment of the blood vessel, as recited on pages 3-5 and seen in figures 2-9G.

Regarding claim 48, Lary discloses a device for percutaneously exposing an outer layer of a body lumen or body cavity of a patient which is covered by an inner layer having a catheter body (22) having a proximal end, a distal end, and a lumen therethrough; and a dissection mean (36) disposed near the distal end of the catheter body for exposing a portion of the outer layer, as recited on pages 3-5 and seen in figures 2-9G.

4. Claims 1-5, 8, 10, 45, and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemelson et al. in US Patent No. 5,728,123.

Regarding claim 1, Lemelson discloses a device having a catheter body (9) having a proximal end, a distal end and a lumen therethrough; and a dissection tool (18) disposed near the distal end of the catheter body, as recited in column 2, lines 35-40, column 2, lines 60-65, columns 3 and 4 and seen in figures 1A-1B, for example. The phrase, "*adapted to expose a portion of the outer layer*" is considered function language

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and does not hold patentable weight in an apparatus claim. Further the device of Lemelson is capable of performing the function. It has been held that the functional language “wherein” and “whereby” statements do not define any structure and accordingly cannot serve to distinguish. In re Mason, 114 USPQ 127, 44 CCPA 937 (1957).

Regarding claim 2, Lemelson discloses that as applied to claim 1. The wherein phrase, *“a body lumen that is a blood vessel, the inner layer is an intimal layer and the outer layer is an adventitial layer”* is considered function language. This “wherein clause is considered to be “[l]anguage that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure [and therefore] does not limit the scope of a claim or claim citation” (See M.P.E.P. 2106, page 2100-7, Rev. 2, July 1996). Thus, the functional phrases are not given patentable weight in an apparatus claim, given the apparatus of Lemelson is capable of performing the function.

Regarding claim 3, Lemelson discloses that as applied to claim 2, as well as, a dissection tool that is a radially expansive element configured to contact the vessel wall in an expanded position, as recited in column 2, lines 35-40, column 2, lines 60-65, columns 3 and 4 and seen in figures 1A-1B, for example.

Regarding claim 4, Lemelson discloses that as applied to claim 3. The wherein phrase, *“a radially expansive element that is a cutting surface configured to cut through the*

intimal layer of the vessel wall to expose a portion of the adventitial layer after contact with the vessel wall in the expanded position” is considered function language. This “wherein clause is considered to be “[l]anguage that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure [and therefore] does not limit the scope of a claim or claim citation” (See M.P.E.P. 2106, page 2100-7, Rev. 2, July 1996). Thus, the functional phrases are not given patentable weight in an apparatus claim, given the apparatus of Lemelson is capable of performing the function.

Regarding claim 5, Lemelson discloses that as applied to claim 4, as well as, a cutting surface that is configured to cut by rotation of the radially expansive element, as recited in column 4, lines 1-20.

Regarding claim 8, Lemelson discloses that as applied to claim 3. The wherein phrase, *“a radially expansive element that is advaceable along the exposed portion of the adventitial layer to delaminate the intimal layer from the adventitial layer along a segment of the blood vessel”* is considered function language. This “wherein clause is considered to be “[l]anguage that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure [and therefore] does not limit the scope of a claim or claim citation” (See M.P.E.P. 2106, page 2100-7, Rev. 2, July 1996). Thus, the functional phrases are not given patentable weight in an apparatus claim, given the apparatus of Lemelson is capable of performing the function.

Regarding claim 10, Lemelson discloses that as applied to claim 3, as well as, a radially expansive element that is expandable by action of an inflatable member, as recited in column 4, lines 1-20.

Regarding claim 45, Lemelson discloses that as applied to claim 2. The wherein phrase, *"a dissection tool that is configured to advance along the exposed portion to delaminate the intimal layer from the adventitial layer along a segment of the blood vessel"* is considered function language. This "wherein clause is considered to be "[l]anguage that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure [and therefore] does not limit the scope of a claim or claim citation" (See M.P.E.P. 2106, page 2100-7, Rev. 2, July 1996). Thus, the functional phrases are not given patentable weight in an apparatus claim, given the apparatus of Lemelson is capable of performing the function.

Regarding claim 48, Lemelson discloses a device having a catheter body (9) having a proximal end, a distal end, and a lumen therethrough; and a dissection means (18) disposed near the distal end of the catheter body, as recited in column 2, lines 35-40, column 2, lines 60-65, columns 3 and 4 and seen in figures 1A-1B, for example. The phrase, *"for exposing a portion of the outer layer"* is considered function language and does not hold patentable weight in an apparatus claim. Further the device of

Lemelson is capable of performing the function. It has been held that the functional language "wherein" and "whereby" statements do not define any structure and accordingly cannot serve to distinguish. In re Mason, 114 USPQ 127, 44 CCPA 937 (1957).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 5 rejected under 35 U.S.C. 103(a) as being unpatentable over Lary in US 2002/0082592.

Regarding claim 5, Lary discloses that as applied to claim 4. However, Lary does not disclose a cutting surface that is configured to cut by rotation of the radially expansive element. On the other hand, rotational endarterectomy devices are extremely well known in the art. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Lary to include a cutting surface that is configured to cut by rotation of the radially expansive element for the purpose of cutting along all surfaces of the interior of the vessel.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US Patent No. 6,565,588; US Patent No. 6,096,054; and US Patent No. 6,066,149.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KO


Henry Bennett
Supervisory Patent Examiner
Group 3700